

Amendments to the Claims:

Claim 1 (currently amended): A process for micronization of a pharmaceutically active agent comprising the steps of:

- (a) suspending the pharmaceutically active agent in a propellant or in a compressed gas,
- (b) processing this suspension by high pressure homogenization, and
- (c) obtaining dry powder upon depressurization.

Claim 2 (currently amended) A process for ~~micronization~~ micronization of a pharmaceutically active agent comprising the steps of:

- (a) suspending the pharmaceutically active agent in a propellant,
- (b) processing this suspension by high pressure homogenization, and
- (c) obtaining a suspension of the micronized pharmaceutically active agent in a propellant.

Claim 3 (currently amended): The process according to claim 1 or 2 wherein the pharmaceutically active agent micronized by said process has an average particle size between about 0.1 and about 7.0 micrometers.

Claim 4 (currently amended): The process according to ~~any preceding~~ claim 1 wherein the pharmaceutically active agent micronized by said process has an average particle size of from about 0.5 to about 5.0 micrometers.

Claim 5 (currently amended): The process according to ~~any preceding~~ claim 1 wherein the suspension formed by the pharmaceutically active agent and the compressed gas or propellant comprises one or more pharmaceutically acceptable excipient.

Claim 6 (currently amended): The process according to ~~any preceding~~ claim 1 wherein the pharmaceutically active agent is poorly soluble in water and/or chemically or thermally unstable.

Claim 7 (currently amended): The process according to ~~any preceding~~ claim 1 wherein the pharmaceutically active agent is chosen from at least one of pimecrolimus (33-Epichloro-33-desoxy-ascomycin), 5-[(R)-2-(5,6-diethyl-indan-2-ylamino)-1-hydroxy-ethyl]-8-hydroxy-(1H)-quinolin-2-one, 3-methylthiophene-2-carboxylic acid (6S,9R,10S,11S,13S,16R,17R)-9-chloro-6-fluoro-11-hydroxy-17-methoxycarbonyl-10,13,16-trimethyl-3-oxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta-[a]phenanthren-17-yl ester, N-benzoylstaurosporine, oxcarbazepine, carbamazepine, 1-(2,6-Difluoro-benzyl)-1H-

[1,2,3]triazole-4-carboxylic acid amide, cox-2 inhibitors, pyrimidylalaminobenzamides, camptothecin derivatives, proteins, peptides, vitamins, steroids, and bronchodilators.

Claim 8 (currently amended): The process according to any preceding claim 1 wherein the compressed gas is chosen from at least one of carbon dioxide, nitrogen, dimethyl ether, ethane, propane and butane.

Claim 9 (currently amended): The process according to any preceding claim 1 wherein the compressed gas is an HFA propellant qualified for human use.

Claim 10 (currently amended): The process according to any preceding claim 1 wherein the compressed gas is chosen from at least one of HFA134a and HFA227.

Claim 11 (original): The process according to claim 5 wherein the pharmaceutically active excipient is chosen from at least one of surfactant, carrier and lubricant.

Claim 12 (original): The process according to claim 11 wherein the surfactant is chosen from at least one of acetylated monoglycerids, perfluorocarboxilic acid, polyethylene glycol (PEG) sterol esters, polyethylene oxide sorbitan fatty acid esters, sorbitan esters, sorbitan mono laurate, sorbitan mono oleate, sorbitan tri oleate, sorbitan mono palmitate, propylene glycol and oleic acid.

Claim 13 (currently amended): The process according to any preceding claim 1 wherein the suspension of the pharmaceutically active agent in a propellant or compressed gas is processed by homogenization using static geometries.

Claim 14 (currently amended): The process according to any preceding claim 1 wherein the suspension of the pharmaceutically active agent in a propellant or compressed gas is processed by homogenization using a dynamic valve.

Claim 15 (currently amended): The process according to any preceding claim 1 wherein the suspension of the pharmaceutically active agent and the compressed gas or propellant is formed in a first stirred vessel and stored in a second stirred vessel after the micronization process.

Claim 16 (currently amended): Micronized A micronized pharmaceutically active agent obtained by the process of any preceding claim 1.

Claim 17 (original): A pharmaceutical composition comprising micronized pharmaceutically active agent obtained by the process of claim 16 and pharmaceutically acceptable excipients.

Claim 18 (original): A package comprising a composition according to claim 17 and instructions to use.

Claim 19 (currently amended): A process according to ~~any one of claims 1 to 15~~ claim 1 wherein said micronized pharmaceutically active agent is prepared in situ in an inhalation device.

Claim 20 – 21 (cancel)

Claim 22 (original) An apparatus for micronization of a pharmaceutically active agent comprising two stirred pressure vessels,
a high pressure homogenizer,
a fluid conduit interconnecting the stirred pressure vessels and the high pressure homogenizer.